Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13072

0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER EDR- 2789 13072
2. DATE 8-22-98

3. FORM OF COMPLAINT	(1) ☒ TELEPHONE (2) ☐ LETTER (3) ☐ VISIT	4. SOURCE OF COMPLAINT	(1) ☒ CONSUMER (2) ☐ TRADE SOURCE (3) ☐ GOVERNMENT (4) ☐ OTHER ☐ L ☐ S ☐ F
5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS (Include Zip Code) [redacted] -15yrs. old)		b. AREA CODE AND TELEPHONE NUMBER HOME ( ) WORK (X [redacted]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY Daughter was behaving in an erratic manner-began tohave heart palpitations, "not acting normal", with bizarre behavior. She was placed in a hosp. by the parents. When checking her room they found a health supplement that she had apparently orded by mail.It appeared that she had ordered 3-30 capsule bottles and that approx. 1 bottle was left. The directions for use on the bottle state "Do not exceed 4 capsules in 24 hours". The ingred. on the label "pyruvic acid (250 mg), Ma Huang (87 mg), garcenia cambogi (17 mg), gymnema sylvestre (17 mg), L-carnitine (10 mg), chromium. The father felt that

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) ☐ NO (2) ☒ YES (Explain in Remarks)

7. INJURY OR ILLNESS RESULTED (1) ☐ NO (2) ☒ YES (If "Yes" complete items b through d)

a. EIB (HFC-161) NOTIFIED (1) ☐ NO (2) ☒ YES DATE: 8-22-98

b. TYPE SYMPTOMS — ONSET(HR)
1. ☐ VOMITING
2. ☐ NAUSEA
3. ☐ DIARRHEA
4. ☐ FEVER
5. ☐ SKIN/EYE IRR
6. ☐ HEADACHE
7. ☒ OTHER bizarre behavior /racing heart/suicidal behavior

c. ATTENDING HEALTH PROFESSIONAL (1) ☐ NO (2) ☐ YES (If "Yes" give name, address & phone number)

d. HOSPITALIZATION REQUIRED (1) ☐ NO (2) ☒ YES (If "Yes" give name, address, phone number & dates) [redacted]

8. PRODUCT AND LABELING

a. BRAND NAME Calor Slim
b. PRODUCT NAME Calor Slim
c. SIZE AND PACKAGE TYPE 30 cap.
d. NAME AND LOCATION OF STORE WHERE PURCHASED see 9 c
e. PACKAGE CODE/SERIAL NUMBER/etc 11619
EXP/USE BY DATE:
f. DATE PURCHASED About 5 weeks ago
g. PRODUCT USED (If "Yes" enter date) (1) ☐ NO (2) ☒ YES since purchase
h. AMT. LEFT 1 bottle

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT
b. C. F. NUMBER
c. NAME AND LOCATION OF FIRM (Include Zip Code) Calor Slim, N.Y., N.Y. aka [redacted]
d. IMPORT PRODUCT (1) ☒ NO (2) ☐ YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD

(1) CODE	(2) DESCRIPTION
RX	ephedra

b. EVALUATION
(1) ☐ NOT AN FDA OBLIGATION
(2) ☐ OBLIGATION. NO VIOL.
(3) ☒ FDA ACTION INDICATED
(4) ☐ INSUFFICIENT INFOR./ UNABLE TO EVALUATE

c. DISPOSITION
(1) ☒ IMMEDIATE FOLLOW-UP
(2) ☐ F/U NEXT E.I.
(3) ☐ CLOSED WITHOUT FURTHER INVESTIGATION
(4) ☐ REFERRED TO OTHER FEDERAL AGENCY
(5) ☐ REFERRED TO STATE/LOCAL AGENCY
(6) ☐ REFERRED TO OTHER FDA ___ DISTRICT
(7) ☐ REFERRED TO OCI

11. PRODUCT CODE 54F--09

12. INFORMATION COPIES TO:
☐ HFM-660 ☐ HFZ-343
☐ HFD-730 ☐ HFC-134
☐ HFV-236 ☐ ___

REMARKS The parent will hold the bottle pending FDA review and is willing to sign medical releases. The aka firm indicated above was obtained (the name) from review of cancelled checks by the parent used to pay for the Calor Slim. The capsules are clear with gray brown powder in the capsules. The daughter reportedly will be in the hosp. for 4 to 6 weeks.

NAME AND TITLE Gary Pierce Dir., DEIO
DATE 8-24-98

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: EDR-2789

2. ACTION REQUESTED
(1) [X] INVESTIGATION
(2) [X] COLLECT SAMPLE
(3) [ ] INSPECTION
(4) [ ] OTHER

(a) REMARKS *(Additional details)*

(b) REQUESTING OFFICIAL'S NAME AND TITLE

(c) DATE REQUESTED

(d) PRODUCT NAME: CALORSLIM

3. ASSIGNED TO: E. Bannerman

(a) DUE BY

4. ACTION TAKEN
(1) [X] INVESTIGATION
(2) [X] SAMPLE COLLECTED
(3) [ ] INSPECTION
(4) [ ] NONE

(a) SAMPLE NUMBER(s): 34926

(b) DESCRIPTION OF ACTION TAKEN

On 11/23/98 investigators met with Mr. [redacted] (complainant and parent of 15 yr. old girl who used suspect product) at his home, [redacted] Credentials were presented and FDA-482, Notice of Inspection, were presented to Mr. [redacted]

Mr. [redacted] daughter, [redacted] was no longer living in the home. [redacted] had been sent to live with relatives in [redacted] and therefore was not available to answer any questions. The following information was provided by [redacted] to the best of his knowledge.

[redacted] purchased at least 4 bottles (30 capsules/bottle) of Calorslim in June 1998, via mail order. This is the only purchase that Mr. [redacted] was aware of, the purchase had been paid for via an electronic transfer of funds from his business checking account. [redacted] had obtained and used the account number without Mr. [redacted] knowledge. It is unknown exactly when [redacted] began using the product, but Mr. [redacted] estimates that it was probably some time in June 1998. Mr. & Mrs. [redacted] did not become aware that [redacted] had the product until they found it in her bedroom in August 1998. [redacted] was reportedly using the product for weight loss.

In July, [redacted] began exhibiting erratic behavior (became phsically aggressive, rebellious, lost touch with reality). Mr. [redacted] stated that at times [redacted] would have physical shaking/ tremors and he thought it may have been due to not eating properly and would bring her juice.

SEE CONTINUATION SHEET SEE CONTINUATION SHEET

(c) ACTION OFFICIAL'S NAME AND TITLE: Eileen J. Bannerman, Investigator CLT-RP/ATL-DO

(d) ACTION DISTRICT: ATL

(e) DATE COMPLETED: 11/23/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST.

(b). CF NO.

(C) NAME AND ADDRESS: Calorslim
aka: L.E.J. Health 2000 Inc.
New York, NY

6. PROGRAM DATA

(a) OPERATION	(b) PAC	(c) PRODUCT CODE		
13	03R801	54FCH09		
(d) EMP. HOME DIST.	(e) EMP. NO.	(f) POS CL.	(g) HOURS	
1	2	2	4	

7. EVALUATION
(0) [ ] PENDING
(1) [ ] NO ACTION INDICATED (NAI)
(2) [ ] VOLUNTARY ACTION INDICATED (VAI)
(3) [ ] OFFICIAL ACTION INDICATED (OAI)
(4) [ ] NOT AN FDA OBLIGATION
(5) [ ] REFERRED TO HOME DISTRICT
(6) [ ] INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION
(1) [ ] FOLLOW-UP NEXT E I
(2) [ ] WARNING LETTER
(3) [ ] CITATION
(4) [ ] SEIZURE
(5) [ ] INJUNCTION/PROSECUTION
(6) [ ] REFERRED TO OTHER AGENCY *(Indicate Agency in Remarks)*
(7) [ ] RECALL
(8) [ ] NO ACTION

9. INFO. COPIES TO
[ ] HFB-100
[ ] HFD-730
[ ] HFV-236
[ ] HFZ-343
[ ] HFC-161
[ ] _____
_____
_____

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL | DISPOSITION | DISPOSITION DATE

FORM FDA 2516a (1/90)

CFSAN Project # 13072

★U.S.GPO:1991-0-312-206/41637

000002

1. COLLECTOR (Print of type name and Signature)	2. DISTRICT	3. CA NO. CC#	4. DATE COLLECTED
Eileen J. Bannerman	ATL	EDR-2789	11/23/98

5. REMARKS

Mr. [redacted] stated that prior to June 1998 [redacted] was a normal 15-yr. old, a little moody and rebellious but not anything unusual for her age. As [redacted] became physically abusive the family became more concerned.

In early August 1998, [redacted] began seeing Dr. [redacted] Mr. [redacted] thinks that Dr. [redacted] prescribed Prozac for [redacted] but [redacted] never used any of it.

In August Mr. [redacted] discovered the Calorslim in [redacted] room. [redacted] behavioral problems increased and on 8/21/98 [redacted] was taken to [redacted] where she was admitted. [redacted] remained at [redacted] until 8/31/98. [redacted] was diagnosed with cyclothymic disorder and was given Depakote.

[redacted] is currently living with relatives in [redacted] and is being treated by Dr [redacted] at [redacted]

Mr. [redacted] voluntarily signed 5 copies of the Authorization for Medical Records Disclosure form, providing authorization for the release of [redacted] medical records.

Mr. [redacted] also provided the remaining product, approximately 22capsules, and all associated labeling and literature. Mr. [redacted] signed the FDA-484, Receipt for Samples. The sample was submitted under sample number 34926. Mr. [redacted] also answered questions for the completion of the Adverse Events Questionnaire.

On 12/7/98 I telephoned the office of Dr. [redacted] Dr. [redacted] stated that he would fax [redacted] records to me upon receipt of the signed medical release form. On 12/7/98 I faxed a signed authorization to Dr. [redacted] and also mailed him an original. Dr. [redacted] provided [redacted] medical records, which have been included as Exhibit #1.

On 12/8/98 [redacted] was visited in an attempt to obtain medical records. This facility requires that their Consent for Release of Medical Information form be completed and signed by the parents. On 12/8/98 attempts were made to contact Mr. [redacted] on his cellular phone [redacted] have been unsuccessful. Directory assistance has no listing for the [redacted] in [redacted] Attempts to contact the [redacted] will continue and any additional medical records will be forwarded upon receipt.

Adverse Event Questionnaire

Complaint Number: EDR-2789 **Investigator:** Eileen Bannerman

Consumer Information

Date of Report: 11/23/98 MM/DD/YY

Initial Report Source: ☒ORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 15

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other_____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: ≈ July 1998 - Aug '98
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product. [redacted] was not available for interview. Information was obtained from her father, [redacted]

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
It is believed that [redacted] began using product in June '98. In July she began exhibiting erratic behavior: physically aggressive; rebellious; lost touch w/reality; inability to sleep; shaking/trembling; anxiety

How long did the symptoms last? ≈ 2 months

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). Parents did not know when [redacted] began using product or how much she used. Product is an oral capsule. [redacted] obtained and used product without parental knowledge. Parents found product in [redacted] room in early Aug.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
None, to the best of the parents knowledge.

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No [redacted]
Give health care provider's name, address and telephone number:
[redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? Full physical; blood work-up; pregnancy test; drug test

What was the medical diagnosis? Cyclothymic disorder

What treatment(s) was given (e.g., drugs, other)?
Therapy (family counseling) + Depakote + Prozac (Kelley refused to take the Prozac)

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

CFSAN Project #13072

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral, a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):
"** CALORSLIM The Miracle Diet Aid *** As a dietary supplement, take 1 capsule daily *** Do not exceed 4 capsules in 24 hours **".

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
Pyruvic Acid 250mg ; Ma Huang 87 mg ; Garcinia Cambogia 17mg ; Gymnema Sylvestre 17mg ; L-Carnitine 10 mg ; Chromium 200 mcg

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☒Other Ephedrine Alkaloids
☐Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒Yes ☐No ☐Unknown Product Sample Available: ☒Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☐No Attempted suicide; suicidal thoughts

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) initial

Required intervention to prevent permanent impairment/damage: ☐Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

CFSAN Project # 13072

000005

Rcvd 1/22/99
DOEP

Department of Health & Human Services
U.S. Food & Drug Administration
Atlanta District

MEMORANDUM

DATE: January 5, 1999

TO: Eric Weilage, ASI
ATL-DO

Bridgette Wallace, Monitor, ARMS
CFSAN

SUBJECT: Additional medical records regarding CC# EDR-2789; CFSAN Project # 13072

FROM: Eileen J. Bannerman, Investigator
CLT-RP/ATL-DO

Attached please find additional medical records collected in response to CC# EDR-2789, as per CFSAN Project # 13072. Please include these records with information previously submitted.

Complete Compliant/Injury Follow-up; Adverse Event Questionnaire; product labeling and medical records were previously submitted. A physical sample of the suspect product, CalorSlim, was also submitted to SEA-Lab, as sample # 34926.

All requested records regarding this consumer complaint have been received and submitted.

Eileen J. Bannerman
Investigator #282
CLT-RP/ATL-DO

1/14/99

To: Monitor, Adverse Reaction Monitoring Systems (ARMS)
FDA / CFSAN; HFS-636

Completed per your assignment Request

Eric S Weilage ASI
ATL-DO

O: CFSAN HFS-636

cc: Charlotte RP